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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,429	09/02/2004	Tsutomu Furuzono	1035-526	1242

23117 7590 06/02/2006

NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER
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PENG, KUO LIANG

ART UNIT	PAPER NUMBER
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1712

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/506,429

Applicant(s)

FURUZONO ET AL.

Examiner

Kuo-Liang Peng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/2/06 Prel. amendment.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/2/06</u>  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The Applicants' preliminary amendment filed on September 2, 2004 is acknowledged. Claims 13-17 are added. Now, Claims 1-17 are pending.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 9, 11, 13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by JP511 (JP 2001-172511).

JP511 discloses a manufacturing method of a hydroxyapatite complex where a hydroxyapatite sintered compact is bonded to a polymer via urea or urethane linkages. The urea or urethane linkages can be derived from a reaction between an isocyanate functional group and an amino or hydroxyl group. ([0011]-[0013], [0016], [0023], [0037] and [0043]) The hydroxyapatite can contain an amino group by treated with a silane coupling agent such as ([0043] and [0049]) The polymer can be surface treated to introduce active groups, followed by grafting through the

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active groups with a ethylenic monomers containing functional groups for reacting with the hydroxyapatite. ([0044]) The polymers can be polysiloxane, etc. that are medical polymeric materials. ([0012] and [0044]) The hydroxyapatite complex can be used for preparing percutaneous trans-catheter, percutaneous terminal, artificial blood vessel and artificial organ. ([0047])

4. Claims 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by JP511 as evidenced by Sato (US 4 276 135).

JP511 discloses a hydroxyapatite complex, supra, which is incorporated herein by reference.

JP511 teaches the use of a silane coupling agent that can be KBE-903 ([0049]. Sato teaches that KBE903 is 3-aminopropyl triethoxysilane. As such, JP511's hydroxyapatite complex does contain the linkage set forth in the instant claims.

5. Claims 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hino (US 5 814 681).

For Claims 9-10, Hino discloses a hydroxyapatite complex prepared by chemically bonding a hydroxyapatite sintered compact with a polymer. (col. 2,

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lines 8-49, col. 3, lines 29-34, col. 3, line 61 to col. 4, line 4) The hydroxyapatite can be surface treated using  $\gamma$ -methacryloxypropyltrimethoxysilan etc. to afford polymerizable groups on the surface thereof. (col. 4, lines 5-39)

For Claims 11-12, the hydroxyapatite complex can be used as a medical material. (col. 1, lines 6-9)

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP511.

JP511 discloses a percutaneous trans-catheter, supra, which is incorporated herein by reference. JP511 is silent on the specific thickness of the hydroxyapatite layer set forth in the instant claim. Note that the thickness of the hydroxyapatite can affect the durability of the layer. In other words, the thickness is a Result-

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Effective variable. Therefore, it would have been obvious to one of ordinary skilled in the art at the time of the invention was made to have a layer of hydroxyapatite on the catheter in whatever thickness through routine experimentation in order to obtain a desirable durability of the hydroxyapatite layer. Especially, Applicants do not show the criticality of the thickness. See MPEP 2144.05 (II).

8. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hino in view of JP511.

Hino discloses a medical material, *supra*, which is incorporated herein by reference. Hino is silent on the specific medical articles set forth in the instant claims. However, JP511 teaches a hydroxyapatite complex as a medical material used for preparing percutaneous trans-catheter, percutaneous terminal, artificial blood vessel and artificial organ. ([0047]) Note that Hino's polymer contain polyoxyalkylene and methacryl moieties. (col. 2, lines 16-49) JP511's polymer can contain polyoxyalkylene and poly(meth)acrylate.([0012]) Since Hino's medical material is substantially the same as that of JP511's, it would have been obvious to one of ordinary skilled in the art at the time of the invention was made

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to utilize Hino's medical material for making JP511's medical articles with expected success. Especially, Hino is in the same field as that of JP511's endeavor.

9. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Furuzono (New development trend of intelligent material/technology -- Chapter5: Percutaneous device).

Furuzono discloses a percutaneous trans-catheter, artificial organ, etc. prepared from a hydroxyapatite complex derived from a hydroxyapatite sintered compact chemically bonded to a polymer (e.g., silk fibroin, etc.) with a linkage set forth in the present invention. (Whole document) Applicants are advised to clarify the publication dates, publisher, etc. of Furuzono.

10. Those lined-through references cited in the information disclosure statement filed on September 2, 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no information on the **publication dates**, **publisher**, etc. thereof. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any resubmission of any item of information contained in this information disclosure statement or the submission of any missing

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element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all requirements for statements under 37 CFR 1.97(e). See MPEP § 609 subsection III, C(1).

11. Applicants are advised that in the response to this Office action, **unless** Applicants clarify that the publication dates, etc. of the aforementioned lined-through references do not render these references as prior art, **Applicants admit these references are prior art**. Therefore, **Final Rejections** based on these references might be applicable later. Especially, some of these references appear to be closely pertinent to the present invention.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (571) 272-1091. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski, can be reached on (571) 272-1302. The

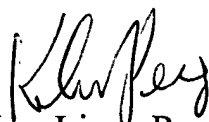


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fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

klp  
May 25, 2006

  
Kuo-Liang Peng  
Primary Examiner  
Art Unit 1712